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McNEIL CONSUMER PRODUCTO COMMITTEE FORT WASHINGTON, PA 19034

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| | | | | O Comment | antion | (6) | | | |
|---|---|--|---|---|---|---------------------------|--------------------------------|------------------------------------|--|
| A. Patient inf | ormation | | 4 19/-1-1-4 | C. Suspect medic | nath & mi | r/labeler, if know | n) | | |
| | 2. Age at time | 3. Sex | 4. Weight | 1. Name (give labeled strength & mfr/labeler, if known) | | | | | |
| | of event: 40 yrs | () female | unk lbs | #1 TYLENOL Analgesic Unknown | | | | • | |
| 01229325 | Dete | | or | #2 | | 12.2 | _ ##1 - | own also duration) | |
| In confidence | of birth: | (X)male | kgs | 2. Dose, frequency & route used 3. Therapy date from/to (or be | | | es (if unknown, give duration) | | |
| B. Adverse event or product problem | | | | | | wn dates or duration | | | |
| . X Adverse event and/or Product problem (e.g., defects/malfunctions) | | | #1 unknown dose, po #1 unknown dates of dollation | | | | | | |
| 2. Outcomes attributed to adverse event | | | 4. Diagnosis for use (indication) | | | 5. Event abated after use | | | |
| (check all that apply) () disability () death () congenital anomaly () life-threatening () required intervention to prevent permanent impairment/damage | | | | #1 abdominal pain | | | stopped or dose reduced | | |
| | | | | | | | #1 () | Yes () No (X) N/A | |
| | | | | 82 | | | | | |
| (X) hospitalization - initial or prolonged () other: | | | | 6. Lot # (if known) 7. Exp. date (if known) | | | 82 () | Yes () No () N/ | |
| 3. Date of event 4. Date of this report | | | #1 Unknown | #1 | Unknown | | reappeared after oduction | | |
| 12/21/9 | 92 | 10/20/98 | | #2 | #2 | | l | | |
| (mo/dey/yr) | (Moraely, 14.) | | | 9. NDC # - for product pro | bleme on | ly (if known) | #1 (-) | Yes () No (X) N/A | |
| 5. Describe event or | bronem | • | | a. MDC # - for product pro | WIGHTS OU | . to many | | Yes () No () N/A | |
| Notification V | Notification via litigation of case summaries provided by | | | | • • | | | | |
| physician/co-author of literature report (N Engl J Med 1997; | | | | 10. Concomitant medical products and therapy dates (exclude treatment of event) | | | | | |
| 337:1112-7). 1 | 337:1112-7). Info provided based on extracted data from | | | | unknown; Sect B6 cont: produced by shadowing form caudate lobe fissure, remainder of liver parenchyma is normal, no | | | | |
| medical records of patients hospitalized for acetaminophen | | | | lobe fissure, re | nalieus | 12/20/02 ACT= | :164 41 | T=540, AlkP=231, | |
| ingestion between 1/1/92 & 4/30/95. According to extracted | | | Clear cut abnor | 110 LLY; 718 TD= | 6.2. Alber 2 | | | | |
| data, a 40 yo fasting pt w/chronic ethanol history was given | | | | T Biti=10, GGT=718, TP=6.2, Alb=3.2 G. All manufacturers | | | | | |
| n unknown qua | intity of acetaminopher | n at the detoxifi | cation | 1. Contact office - name/s | ddress (8 | k mfring site for d | levices) | 2. Phone number | |
| showed LIVER FUNCTION TESTS ABNORMAL & PROTHROMBIN INCREASE. Pt d/c on 12/29/92. Addl info rec'd 10/13/98: Med records indicate pt complained of 2-3 day hx of NAUSEA and VOMITING, JAUNDICE & DEHYDRATION. Pt experiencing tremors of alcohol withdrawal on arrival to ER. Pt treated w/ IV fluids, multivitamins w/ iron, thiamine, folate & LIBRIUMO | | | McNeil Consumer Products Company 215-233-7820 | | | | | | |
| | | | Medical Affairs | | | | 3. Report source | | |
| | | | 7050 Camp Hill | | (check all that apply | | | | |
| | | | Ft. Washington, PA 19034 | | | | () foreign | | |
| | | | | | | | () study | | |
| | | | | | () literature | | | | |
| taper. Over next few days pt's LFTs & alcohol withdrawal | | | | , | 4 | () consumer | | | |
| gradually imp | roved. According to d/ | c summary a live | r consult | | | | | health | |
| gradually improved. According to d/c summary a liver consult indicated "the picture was consistent w/TYLENOL-alcohol | | | | 4. Date received by manufacturer 5. | | | | (x) professional () user facility | |
| syndrome". Principal dx: alcoholic hepatitis. | | | 10/13/98 (A) NDA # 17 | | | 226 | () user facility | | |
| | | 6. If IND, protocol # IND # | | | | en saily | | | |
| | | | | 4 | ļ | PLA # pre-1938 (|) Yes | () distributor | |
| | aboratory data, including dat | | | <u></u> | | pro .000 (| , | () other: | |
| 12/24/92 Crea | t=3.4, AST=6400, ALT=2 | 2684, T Bili=22.1 | inambre- | 7. Type of report (check all that apply) | | OTC product () | X) Yes | | |
| GGT=476, TP=6 | .4, ALB=3.9, PT=17.8; | PTT=35.3, acetar | inoprien | () 6-day (X)15-dar | , l | | | | |
| level=3, ETOH | level=neg; HBSAG, ANT | I-HBC, ANII-HAV | sect (10) | () 10-day () period | 1 | 8. Adverse event | term(s) | | |
| reactive); U/S-hypoechoic caudate lobe may be (see sect C10) | | | | () Initial (X) follow-up # 1 HEPATITIS | | | NAUSEA YOMIT | | |
| | | | JAUNDICE | | | DEHYDRATION | | | |
| | | | | 9. Mfr. report number LIVER FUN | | | C ABNO PROTHROMBIN IN | | |
| | | | | 0904092A | | | | | |
| 7. Other relevant I | history, including preexisting | medical conditions (e hepatic/renal dysfund | e.g., allergies, tion, etc.) | E. Initial reporte | | | | | |
| admits to drinking approximately 3 beers per day & 2-3 scotches per day for the past 6 years & has drunk consistently since the age of 25; 6 yr hx of intermittent | | | | 1. Name, address & phone # | | | | | |
| | | | | | | | | | |
| | | | | abdominal pa | in associated w/ eleva | ted LFTs, this l | iver | | |
| roblem prev | iously attributed to p | | | | 14 1-141 4 | l consiste also | | | |
| | atitis at 10 yrs old | | | 2. Health professional? | 3. Occup | ation | 4. Initial | reporter also report to FDA | |
| | | report does not con | stitute an | | | ician | | Yes () No (X) Unk | |
| | admission that m | edical personnel, u | ser facility, | (X) Yes () No | i buas | sician | | , , , ,,, | |



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.